

# RESEARCH

## Provision of rapid HIV tests within a health service and frequency of HIV testing among men who have sex with men: randomised controlled trial

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### Abstract

**Objective** To determine if the provision of rapid HIV testing to men who have sex with men attending a health service would increase their frequency of HIV testing over time.

**Design** Non-blinded randomised controlled trial.

**Setting** Public sexual health service in Australia.

**Participants** Men who reported having a male sexual partner within the previous year and an HIV test within the previous two years. Of 400 men entered, 370 (92.5%) completed the study.

**Interventions** Men attending the service between September 2010 and March 2011 were randomised 1:1 to either ongoing access to rapid HIV testing obtained with finger prick or to conventional HIV serology with venepuncture, over 18 months.

**Main outcome measure** The incidence of all HIV testing after enrolment, including testing outside the study clinic, analysed by intention to treat.

**Results** Of 200 men randomised to the rapid testing arm, 196 were followed for 288 person years. Of 200 men randomised to the conventional testing arm, 194 were followed for 278 person years. Median time since the last HIV test was six months for both arms. Men in the rapid test arm had 469 tests (mean 1.63 tests a year), and men in the conventional test arm had 396 tests (mean 1.42 tests a year); incidence rate ratio 1.15, 95% confidence interval 0.96 to 1.38;  $P=0.12$ . In a post hoc analysis, rates of initial HIV testing during follow-up were 1.32 and 1.01 tests a year, respectively (1.32, 1.05 to 1.65;  $P=0.02$ ).

**Conclusions** Provision of access to rapid HIV testing in a health service did not result in a sustained increase over time in HIV testing by men who have sex with men; however, the rate of initial HIV testing did increase by a third. Further research is required to determine how to

achieve sustained increases in the frequency of HIV testing by populations at risk.

**Trial registration** ACTR No 12610000430033.

### Introduction

In many countries the prevalence and incidence of HIV remains high among men who have sex with men, despite prevention campaigns.<sup>1-4</sup> Increased HIV testing in these men could help to stem HIV transmission because awareness of positive HIV status could reduce sexual risk behaviour<sup>5,6</sup> and because timely diagnosis provides an opportunity for earlier antiretroviral therapy, which would maximise the impact of treatment as prevention.<sup>7</sup> The potential impact of HIV testing on transmission in a population depends in part on the proportion of infected individuals who are unaware of their HIV status. Mathematical models suggest that over 50% of HIV transmissions in the United States were from undiagnosed individuals<sup>8</sup> and that more frequent HIV testing would reduce transmissions.<sup>9,10</sup> Seroprevalence surveys and surveillance indicate that 12-30% of HIV positive men who have sex with men in Australia, Canada, and New Zealand remain undiagnosed, rising to 44% in the US and 86% in one survey from China.<sup>11-17</sup>

Guidelines recommend that men who have sex with men should have at least annual HIV testing, with more frequent testing in men at higher risk.<sup>18-20</sup> The public health benefits resulting from early diagnosis, treatment, and behaviour change are likely to be greater with more frequent testing because HIV is most infectious around the time of seroconversion, when the viral load is highest.<sup>21,22</sup> Data from high and middle income countries indicate that rates of HIV testing among men who have sex with men often fall short of the levels recommended.<sup>18,23-25</sup>

Several impediments to HIV testing of men who have sex with men have been identified. These include fear of a positive result, anxiety while waiting for a result, difficulty in accessing services for testing, and the need to return to obtain results.<sup>26 27</sup> Not all those infected with HIV who attend a clinic will be tested and diagnosed.<sup>28</sup> Point of care tests for HIV, commonly referred to as rapid HIV tests, have the potential to improve the uptake of testing because of the immediacy of test results. When surveyed, most men who have sex with men in Melbourne anticipated they would test more frequently if oral fluid rapid HIV tests were available. In 2012 the US Food and Drug Administration approved the sale of self administered oral fluid tests in an effort to increase testing and reduce the pool of people with undiagnosed HIV.<sup>29 30</sup>

Several studies have shown that rapid tests increase uptake of HIV testing in various settings, though these have been cross sectional studies comparing the uptake of a rapid or conventional HIV test on a single occasion without examining the frequency of testing after the first test.<sup>31-35</sup> To date there is no empirical evidence that the provision of rapid tests leads to a sustained increase in the frequency of HIV testing over time in any population. We undertook a randomised controlled trial to determine whether the provision of rapid tests for HIV within a health service would increase the frequency of HIV testing among men who have sex with men.

## Methods

### Trial design

In this non-blinded trial, the men were randomised in a 1:1 ratio to either ongoing access at the health service to rapid tests for HIV (intervention) or to conventional HIV testing (control) at the same health service over an 18 month period. Recruitment took place from September 2010 to March 2011 with the last participant completing 18 months of follow-up in September 2012.

### Participants

This study took place at the Melbourne Sexual Health Centre, the major public clinic for sexually transmitted diseases in Victoria, Australia. Eligible participants were men aged  $\geq 18$  attending for clinical care who reported having sex with a man within the previous year and who had had a negative HIV test result within the previous two years. To increase the likelihood that men would retest within the study period we recruited only men who had been tested for HIV within the previous two years. Men seeking post-exposure prophylaxis for HIV were excluded from the study as were those planning to live outside Victoria for more than six months.

### Interventions

Men randomised to the intervention arm were tested at enrolment with the Determine HIV-1/2 Antigen/Antibody Combo test (Alere, Japan) in whole blood obtained from finger pricks. These men were informed that they could attend the clinic at any time over the subsequent 18 months to be tested for HIV with a rapid test. Men randomised to the control arm were offered the clinic's standard HIV test: venepuncture with serum forwarded to the Victorian Infectious Diseases Reference Laboratory for testing by third generation enzyme immunoassay (Murex, Dartford, UK). Men in the control arm were required to return to the clinic one week after the test so they could be given the HIV result in person. Men tested with rapid tests received their result 20 minutes after the finger prick.

The clinic protocol governing testing for HIV and sexually transmitted infections in men who have sex with men followed Australian guidelines—namely, annual screening for HIV, syphilis, pharyngeal and rectal gonorrhoea, and urethral and rectal chlamydia, with three to six monthly screening of men at higher risk.<sup>19</sup> Screening for syphilis was undertaken by venepuncture and serology. Men in both arms were required to undergo venepuncture if they agreed to syphilis testing.

Reactive antibody results on rapid testing were confirmed by the Murex third generation enzyme immunoassay—the Genscreen antigen-antibody HIV test (Bio-Rad, France)—and by western blot. Indeterminate results were resolved by testing of a further serum sample obtained at least two weeks later. Reactive rapid antigen results were confirmed by P24 antigen EIA (Bio-Rad, France).

Men in both arms of the study were managed in the same way according to the standard clinical pathways and management protocols when they attended for subsequent visits, apart from the type of HIV test that they could have. This included access to the clinic without a previous appointment and brief assessment by a triage nurse followed by a consultation with a nurse or doctor who then discussed and offered testing for sexually transmitted infections and HIV. Men having an HIV test were referred to a nurse who performed the finger prick test for men in the intervention arm or venepuncture for men in the control arm. Men in the intervention arm were free to have conventional HIV testing if they wanted.

Men in both arms of the study were sent text messages at months three, nine, and 15 of the study recommending regular HIV testing and offering either an “HIV test” or a “rapid HIV test” at the study clinic, according to their allocated arm. They were also referred via the text message to a website that was specific for their allocated arm to remind them of the type of testing available to them and were given a dedicated study phone number for inquiries. The electronic clinic medical records were marked to indicate to clinicians that patients were participants in the trial and noted the arm to which they had been allocated. Men in both arms received email messages at months six, 12, and 18 containing a link to an online study questionnaire. A \$A20 (£12, €14, \$18) voucher was offered to participants who completed all questionnaires.

### Outcomes

Our primary outcome was the frequency (incidence rate) of HIV testing over 18 months, expressed as number of tests per person year, excluding tests performed at enrolment. HIV testing included HIV testing performed at the study clinic, whether rapid or conventional, as well as HIV testing performed by healthcare providers at other clinics. No rapid tests for HIV were approved for clinical use in Australia during the study period and therefore all testing at other sites would have been through conventional serology. HIV testing and results were recorded in the electronic medical records system.

Men were asked via the online questionnaires if they had been tested for HIV elsewhere and, if so, when and where this had taken place. If questionnaires were not completed this information was obtained through text messages sent to individual men. Researchers then contacted external clinics to verify that HIV testing had occurred and the date of testing. The online questionnaires included questions about attitudes to HIV testing and sexual behaviour. Participants were also asked how they felt about their HIV test experience. The secondary outcome was the frequency (incidence rate) of testing for syphilis, gonorrhoea, and chlamydia to determine if rapid HIV testing

would result in a fall in testing for other sexually transmitted infections.

## Sample size

Before this study the mean interval between HIV tests among men who have sex with men who were attending the clinic and who had previously tested within the past two years was 12 months (SD 5 months). A 10% increase in the proportion of men tested annually would have reduced the interval between tests by six weeks. Because modelling of the Australian HIV epidemic suggested that a 10% increase would avert 13 new HIV infections each year, we powered the study to detect a minimum difference in interval between tests of six weeks.<sup>10</sup> If we assume a mean interval between HIV tests of 12 months, a study with 174 people in each arm would have 80% power to detect a 1.5 month reduction in this interval at a significance of 0.05.

## Randomisation and blinding

Participants were randomised with a randomised block design with two computer generated random sequences per block (prepared by JSH) to ensure there would be equal numbers allocated to each study arm. A research assistant not associated with the trial sealed study allocations in numbered opaque envelopes that were opened in sequence at the time each man was enrolled. Research personnel who enrolled participants and assigned interventions (AM and TRHR) were unaware of the allocation until the envelope was opened in front of the patient. The study design required participants and clinic staff to be aware of the allocated type of HIV test.

## Statistical methods

We calculated the incidence of HIV testing with intention to treat analysis after excluding individuals with positive HIV test results at enrolment. Men who did not have a subsequent test and those who were lost to follow-up were censored at their last contact when questionnaires were sent at six months, 12 months, or at study end at 18 months. Men who developed incident HIV infection during follow-up were censored at the time of their new positive test result. Confirmatory HIV testing was excluded from the analysis. We used Poisson regression methods to estimate the ratio of incidence rates of HIV testing in the rapid test arm compared with the control arm and calculated robust standard errors to account for repeated measures from individuals. Proportions and 95% confidence intervals were calculated with binomial exact methods. Differences between proportions were investigated with the  $\chi^2$  statistics. Analyses were undertaken with Stata version 11.

## Results

From September 2010 to March 2011, clinicians referred 445 men to the study. Of these men, 26 declined to participate (fig 1). Nineteen men were found to be ineligible, mainly because they were not planning to reside within Victoria during the study period. Of the 400 men who were recruited and randomised, 200 were assigned to HIV rapid testing and 200 to conventional testing. Among the 200 men randomised to rapid testing, five had a diagnosis of with HIV (two at baseline), six were lost to follow-up, and 189 (94.5%) completed 18 months of follow-up. Among the 200 men randomised to conventional testing five had a diagnosis of HIV (three at baseline), 14 were lost to follow up, and 181 (90.5%) completed 18 months of follow-up (fig 1). The 10 men with a diagnosis of HIV were censored at the date of their positive result. Five were positive at enrolment

(overall baseline prevalence 1.25%, (95% confidence interval 0.4% to 2.9%) and five were incident cases (overall incidence 0.9% a year, 0.3% to 2.1%). Table 1 compares the characteristics of men in the intervention and control arms.

Men assigned to the rapid test arm had 469 tests during 288 person years of follow-up while men in the conventional test arm had 396 tests during 278 person years of follow-up. After enrolment, the incidence of HIV testing in the rapid and conventional test arms over 18 months was 1.63 and 1.42 tests a year, respectively, representing an incidence rate ratio of 1.15 (95% confidence interval 0.96 to 1.38;  $P=0.12$ ) (table 2). When we included only the first HIV test after enrolment in a post hoc analysis, the rate of HIV testing in the rapid test arm was higher than in the conventional test arms. The rate was 1.32 tests a year (161 tests/122 person years) in the rapid test arm and 1.01 tests a year (141 tests/140 person years) in the conventional test arm, representing an incidence rate ratio of 1.32 (10.5 to 1.65;  $P=0.02$ ; table 2, fig 2). When we excluded the first HIV test after enrolment, the rate of subsequent HIV testing was the same in both arms, at 1.86 tests a year in the rapid arm and 1.83 tests a year in the conventional arm (1.01, 0.86 to 1.20;  $P=0.90$ ).

The rate of testing for syphilis, chlamydia, and gonorrhoea at the study clinic did not differ significantly between study arms. The rates of syphilis testing in the intervention and control arms were 1.42 and 1.32 tests a year, respectively (incidence rate ratio 1.13, 95% confidence interval 0.95 to 1.35;  $P=0.18$ ), while the rates of testing for chlamydia and gonorrhoea were 1.56 and 1.42 a year, respectively (1.11, 0.90 to 1.36;  $P=0.33$ ).

Unconfirmed reactive tests, representing false positive results, were more common with rapid tests than with conventional serology (9/596, 1.5% (95% confidence interval 0.6% to 2.8%) v 1/534, 0.2% (0% to 1.0%);  $P=0.02$ ). Of 417 tests performed in the study clinic after enrolment in the rapid test arm, 396 (95%) were rapid tests and 21 (5%) were conventional tests. Reasons for the performance of conventional tests among participants in the rapid test arm included declined rapid testing after a previous false positive rapid test result ( $n=5$ ), declined rapid testing without providing a reason ( $n=6$ ), and clinic staff were unaware of the study ( $n=5$ ).

At the baseline visit, men in the intervention arm were asked about their preference for HIV testing after they had experienced the finger prick test. Most men (167/190, 88%, 95% confidence interval 82% to 92%) said they preferred rapid tests over conventional HIV testing. The final study questionnaire was completed by 270/390 (69%) of the men who remained HIV negative throughout the study: 142/195 (73%) in the rapid test arm and 128/195 (66%) in the conventional serology arm ( $P=0.10$ ). Compared with men randomised to rapid tests, men with access only to conventional serology were more likely to feel that the wait for the test result was too long (75/128 (59%) v 13/142 (9%),  $P<0.001$ ), to report anxiety because of the wait (81/128 (63%) v 63/142 (44%),  $P=0.002$ ), and to report delaying their next test because of anxiety over the wait (30/127 (24%) v 19/142 (13%),  $P=0.03$ ). More men randomised to rapid tests reported that obtaining their HIV test result was convenient (105/141 (74%) v 52/128 (41%),  $P<0.001$ ).

## Discussion

In this study, provision of rapid HIV testing to men who have sex with men attending a health service did not result in a sustained increase in their frequency of testing over time when compared with conventional HIV testing. In a post hoc analysis, however, the rate of initial HIV testing did increase by a third. To our knowledge this is the first randomised controlled trial

to measure the effect of an intervention on the frequency of HIV testing in a cohort of individuals followed over time. Our findings have implications for the development and evaluation of new approaches, including the use of rapid testing, aimed at achieving sustainable increases in HIV testing within populations at risk.

Several aspects of this study need to be considered in the interpretation of the results and their relevance to other settings. Firstly, rapid tests had to be performed in the clinic after a clinical consultation, which kept participants in the clinic longer than would have been necessary for rapid testing alone. The time required for this process could have deterred more frequent testing in the rapid test arm. Secondly, we enrolled men who had been tested for HIV within the past two years and were therefore predisposed to testing. Rapid testing might have a greater effect on the testing frequency of men who have never had HIV tests or who test less frequently than the men in our study. Furthermore, men undergoing conventional HIV testing were required to return to the clinic for their results. This could have discouraged more frequent testing in the conventional HIV testing arm and increased the apparent effect of the intervention. The intervention might have had less effect in a health service that did not require a return visit for test results. Finally, the study was powered to detect a six week reduction in the mean interval between HIV tests, which we determined would probably only deliver a marginal public health benefit for men who have sex with men in Australia. But a smaller change in the interval between tests could be important in populations with a higher incidence of HIV, as seen in some epidemics in resource poor countries.

## Results in context

Other studies have compared the acceptance of rapid and conventional HIV tests but differ from ours as they have measured uptake on only one occasion, without examining whether uptake is sustained over time. In these studies, which include randomised trials in diverse settings, the uptake of rapid testing was consistently higher.<sup>31 32 34 35</sup> In addition to greater uptake of testing, a higher proportion of those undergoing rapid HIV testing received their test results compared with those who had conventional tests.<sup>31 33 35</sup> In one randomised study, acceptance of HIV testing did not differ between individuals offered oral fluid and finger prick rapid tests,<sup>32</sup> suggesting that use of rapid finger prick testing rather than oral fluid testing in this study was unlikely to have reduced the effect of the intervention. Randomised trials of other interventions—such as educational videos or mobile testing services—have examined the proportion of a population having one or more tests after an intervention but have not followed the testing frequency of individuals over an extended period.<sup>36 37</sup> Interventions aimed at increasing HIV testing need to achieve sustained increases if they are to confer meaningful individual and public health benefits. Evaluations need to assess the durability of such interventions over time.

Men who had access to the rapid HIV tests in our study preferred them over conventional tests and expressed less concern about some of the recognised barriers to HIV testing, such as the wait for the test result and the inconvenience of testing. This probably explains the observed higher rate of return for initial HIV testing after enrolment. But simply offering rapid testing within a health service was not enough to bring about a sustained rise in testing. Policymakers and clinicians should be cautious about assuming this will occur without considering the setting. Rapid tests might be more effective in locations that are more easily accessible to target populations, such as shop front testing sites or even at

home. One advantage of rapid HIV tests is that they improve the likelihood that HIV positive individuals receive their results. Though this is important in settings where effective provision of results is difficult, it rarely occurred in our setting and was therefore not a study outcome.<sup>38</sup>

Men who have sex with men remain one of the major risk groups for HIV globally and strategies to reduce the number of undiagnosed HIV infections are urgently required. Whether provision of rapid testing in countries with good access to laboratory HIV testing will boost the frequency of HIV testing is not known. Studies of novel, cost effective strategies to reduce barriers to HIV testing and enhance testing among men who have sex with men and other populations at risk are needed. It is vital that such studies are conducted with a sufficiently long follow-up period to determine the durability of their effect.

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Contributors: TRHR, CKF, and MYC designed and were principal investigators of the study, with assistance from CSB. AM performed most of the rapid tests, confirmed tests performed elsewhere, and collated data for this study. JSH and TRHR analysed the data, with advice from AEG. All authors contributed to the final report. CKF and MYC are joint last authors. TRHR and MYC are guarantors.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/doi\\_disclosure.pdf](http://www.icmje.org/doi_disclosure.pdf) (available on request from the corresponding author) and declare that Alere (Australia and New Zealand) provided free rapid test kits and provided advice on quality control but had no input into the design, analysis or reporting of this study.

Ethical approval: This study was approved by the Alfred Hospital research ethics committee (study 171/10), and all participants gave informed consent.

Data sharing: Study protocol and de-identified data are available from the corresponding author.

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**What is already known on this topic**

Increased HIV testing in at risk populations is required to help stem further HIV transmission

Rates of testing in many countries remain low, with HIV remaining undiagnosed in a substantial proportion of infected people

**What this study adds**

In a randomised trial, men who have sex with men who were offered point of care testing for HIV did not have a significantly higher rate of HIV testing than those accessing conventional HIV testing over 18 months' follow-up

Post hoc analysis showed an initial increase in their rate of testing that was not sustained

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## Tables

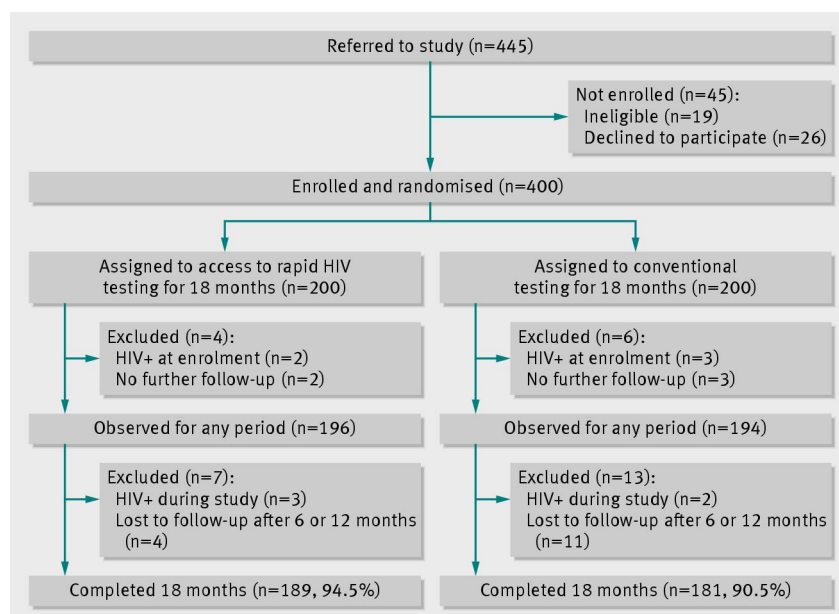
**Table 1** | Characteristics of men who have sex with men at enrolment in study of effect of rapid point of care HIV tests on frequency of HIV testing in public health service in Australia. Figures are medians unless stated otherwise

	Rapid HIV test (n=200)	Conventional HIV test (n=200)
Age (years)	30	29
Time since last HIV test (months)	6	6
No (%) university educated	114 (57)	99 (50)
No of male sex partners in previous year	10	8
No of male anal sex partners in previous year	5	5
No (%) reporting any unprotected anal sex with casual partners in previous year	89 (46)	80 (42)

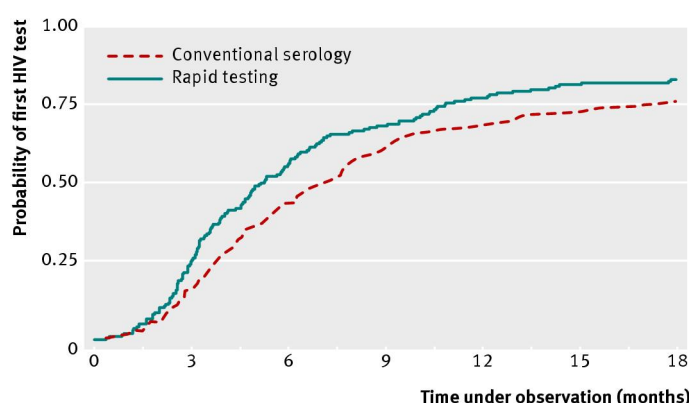
**Table 2| Incidence rate of HIV testing over time among men who have sex with men according to allocation to rapid HIV test or conventional HIV test in public health service in Australia**

Outcome	Rapid HIV test			Conventional HIV test			Incidence rate ratio (95% CI)	P value
	No of tests	Person years	Tests/year (95% CI)	No of tests	Person years	Tests/year (95% CI)		
HIV tests over 18 months	469	288	1.63 (1.49 to 1.79)	396	278	1.42 (1.29 to 1.57)	1.15 (0.96 to 1.38)	0.12
First HIV test after enrolment test	161	122	1.32 (1.13 to 1.54)	141	140	1.01 (0.86 to 1.19)	1.32 (1.05 to 1.65)	0.02
Subsequent HIV tests (excluding first tests)	308	166	1.86 (1.66 to 2.07)	255	139	1.83 (1.62 to 2.07)	1.01 (0.86 to 1.20)	0.90

## Figures



**Fig 1** Screening, enrolment, randomisation, and follow-up of men who have sex with men in study of effect of provision of rapid HIV testing on frequency of tests



**Fig 2** Kaplan-Meier estimates showing probability over time of first HIV test undertaken after baseline testing. Curve shows proportion of tests as they occur over 18 months